Boston Public Health Commission

Biological Laboratory Safety Permit Application

SECTION 10: BSL-4 LABORATORY INSPECTION PROGRAM

Boston University

National Emerging Infectious Diseases Laboratories

November 2014

CONTENTS

Boston Public Health Commission

Biological Laboratory Safety Permit Application

SECTION 10: BSL-4 LABORATORY INSPECTION PROGRAM

Boston University Medical Center

National Emerging Infectious Diseases Laboratories

November 2014

1.0 PURPOSES AND APPLICABILITY

Research laboratory activities use a variety of hazardous substances (e.g., chemical, biological, radiological); equipment that is potentially hazardous (e.g., X-rays or lasers); procedures that have the potential to cause physical injuries (e.g., use of pressurized vessels, vacuum systems); or materials that have the potential to create general fire or life safety hazards (e.g., flammable materials, electrical and electronic equipment).

All activities in a Biosafety Level 4 (BSL-4) laboratory are governed by myriad regulations that have been promulgated by local, state, or federal agencies. Many of these regulations require oversight provisions that mandate:

- The submission of an application for review and approval (e.g., biological materials use);
- Tracking of activities post approval (e.g., environmental health and safety surveillance) and periodic reviews, audits, and inspections;
- Maintenance of detailed inventories of hazardous materials (e.g., biological, chemical or radiological), animals, and controlled substances;
- Training programs for individuals engaged in research activities;
- Unannounced inspections by the regulatory agencies.

2.0 POST-APPROVAL MONITORING

“Post-approval monitoring” is the term used to describe the programmatic approach implemented to ensure that the approved research activities conducted in NEIDL BSL-4 laboratories are conducted in accordance with the terms and conditions of the approval and the regulatory framework that governs such activities. Monitoring and verifications are done both internally by Boston University Environmental Health & Safety (EHS) and externally by the applicable regulatory agencies, including the Centers for

Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), the Boston Public Health Commission (BPHC), and other agencies.

The Comprehensive Laboratory Audits for Safety (CLAS) program is developed to meet the post-approval monitoring and verification requirements and as a mechanism to:

- Evaluate the effectiveness of the NEIDL Laboratory Safety Program;
- Ensure early identification of potential issues and implementation of corrective actions;
- Determine the compliance of laboratory personnel with the procedures and processes that are implemented for the safe handling of hazardous material and laboratory operations;
- Provide an interface between EHS and the BSL-4 laboratory;
- Identify and remediate programmatic areas in need of improvement;
- Develop new or enhance existing training programs to reinforce the culture of safety.

These audits, conducted by EHS staff, laboratory personnel, Facilities Management & Planning (FMP), and others include a thorough review of the administrative requirements of the programs, training records, usage and storage procedures, and personal protective equipment as well as surveys and wipe testing of the laboratories.

CLAS is designed to meet a number of goals:

1. Provide a comprehensive evaluation of the safety programs in a given laboratory;
2. Address issues of health and safety in an integrated and holistic manner and hence improve overall safety;
3. Allow for identification of trends in individual or overall safety programs.

The philosophy of the CLAS program is to educate and support the research community's awareness of safe laboratory practices and regulatory obligations, and to minimize workplace hazards.

The program covers all hazardous materials and physical hazards (e.g., radioactive, biological, chemical; fire and life safety) and is intended to provide two levels of information:

1. Routine update on hazardous materials used, users, use locations, equipment, etc.
2. Review of safe handling procedures and practices for hazardous materials used in the NEIDL.

BSL-4 laboratory inspections are subject to distinct performance evaluations by: 1) authorized laboratory workers, Principal Investigators (PIs), and Core Supervisors; 2) FMP personnel; 3) EHS; 4) veterinary staff, and 5) other support staff. Each evaluation will entail defined and specific checklists (e.g., facilities monitoring and evaluation of laboratory pressurization through systems controls).

3.0 ROLES AND RESPONSIBILITIES

3.1 Environmental Health & Safety

Environmental Health & Safety (EHS) is responsible for the daily pre-operational checks of life safety and critical containment systems that support the BSL-4 maximum containment. These systems are outside of the maximum containment barrier and are checked to assure for their operational readiness prior to the start of daily research operations. The pre-operational check includes review of BAS system generated report alarms. EHS also conducts semi-annual comprehensive review of the maximum containment facility which include the review of relevant records and physical inspection of the facility to assess the containment status and condition; inspection of equipment condition and use; and review of practices and procedures performed by personnel. The inspection is based on the CDC/USDA *Inspection Checklist for BSL-4 Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; BMBL 5th Edition).*

3.2 Core Director

The Core Director is the primary responsible person with overall oversight of the Core. The Director works with the Core Supervisor to ensure the implementation of set safety procedures and practices within the laboratory are strictly followed to ensure for safety of personnel and security of agents; works with EHS to ensure that all corrective actions identified during inspections are addressed appropriately and on time; ensure that findings are communicated to staffs and that staffs are appropriately trained as necessary on any corrective actions taken to ensure that it does not re-occur; works with Facilities and EHS to schedule annual recertification of the facility; and reports any incidents or accidents that occurs in the facility to EHS and Director of NEIDL.

3.3 Principal Investigator

The Principal Investigator (PI) is responsible for ensuring that all personnel have successfully completed their BSL-4 training and mentor-training program as defined in Section 15: Training Plan before they can work without mentor supervision in a BSL-4 facility. The PI will ensure that all personnel follow the strict laboratory safety operational procedures that are implemented in the laboratory. The PI is also responsible for registering research projects with the appropriate safety and scientific advisory committees before work can begin. He or she must keep and update all records, as necessary.

3.4 Responsible Official

The Responsible Official (RO) is an authorized individual with responsibility, authority, and control to ensure compliance with institutional policies and CDC and Animal and Plant Health Inspection Services (APHIS) Rules and Regulations pertaining to the safety, inspection, and operations of the BSL-4 laboratories. BU/BMC has designated the Director of Research Safety as

the CDC RO pertaining to the possession, use, and transfer of Select Agents and Toxins, and will report the results of these efforts to CDC and APHIS.

3.5 Associate Vice President for Research Compliance

The Associate Vice President for Research Compliance (AVP-RC) has oversight for the control of hazards in the research laboratories and for ensuring that comprehensive, enterprise-wide programs are in place for the safe handling of all hazardous (e.g., biological, chemical, radiological, etc.) materials; all non-financial research compliance at BU and BMC; the Institutional Biosafety Committee (IBC), Biosafety Program, Research Occupational Health Program, Laboratory Safety Committee (LSC), laboratory animal use and care programs (Institutional Animal Care and Use Committee (IACUC), and the animal care programs on both the Medical and Charles River Campuses), and other research-related oversight committees.

The AVP-RC acts as the Responsible Official (RO) for the City of Boston's Public Health Commission Laboratory Regulation and ensures communication between the IBC, Charles River Institutional Review Board (IRB), IACUC, and regulatory agencies (e.g., City of Boston, CDC).

3.6 Quality Representative

The Quality Representative (QR) conducts a high-level independent review of systems and operational processes in BSL-4 laboratories. The QR helps facilitate the design and validation of efficient workflow processes, conduct meetings on quality and promote the culture of safety through quality assurance. The QR is responsible for the oversight and management of the document control management system. The system is used to manage the process for development, review and implementation of Standard Operating Procedures (SOP). The Quality Representative's role in the inspection process includes the quality review of the inspection process, that remediation of any safety issues identified is carried out promptly and that the inspection and follow up documentation is collected appropriately and the records are maintained. Thus, the review provides a top-level assessment of the research safety operations and building system control process to ensure that every aspect meets or exceeds the intended design and outcome. The Quality Representative reports to NEIDL leadership independently from EHS.

3.7 Director, NEIDL Facilities

The Director, NEIDL Facilities, is responsible for coordinating the maintenance of the BSL-4 laboratories. The Director's responsibilities include preventive and corrective maintenance, improvement projects and the monitoring and evaluation of building systems. The Director is ultimately responsible for reviewing facilities-related problems and determining the best course of action, including both in-house and contract services.

3.8 BSL-4 Laboratory Authorized Individuals

All personnel authorized to work in BSL-4 environments are responsible for maintaining proper hygiene and working safely and in compliance with appropriate regulations and guidelines. In addition, authorized individuals are responsible for notifying appropriate representative (e.g., EHS, Public Safety, PI) if there is a potential safety or security hazard to facilitate a prompt follow-up and corrective action.

3.9 Core Supervisor

The Core Supervisor (CS) acts as the laboratory safety coordinator and is designated by the Core Director to oversee implementation of safety practices and adherence to them in the laboratory's research operations. The CS works with EHS to ensure all laboratory personnel maintain strict adherence to standard laboratory safety procedures; oversees and ensures that laboratory equipment used for biohazardous materials are properly maintained for continued safe operations; works with the Core Director and PI to manage and maintain safe laboratory operations by conducting biannual (twice yearly) verifications and inspections of the Core facility, support spaces, and operations. The biannual inspections performed by each of the Cores and EHS are the basis for CLAS.

3.10 Director, Animal Core

The Director of NEIDL Animal Core has the responsibility for the care of animals used in the experiments in the BSL-4 laboratories. The Director ensures that animal care staffs are trained and competent to both conduct work and to use the related necessary equipment in the containment facility, and he or she maintains and updates associated recordkeeping.

4.0 INSPECTION METHODOLOGY

The inspection methodology associated with the NEIDL BSL-4 laboratories includes specific inspection plans conducted by trained personnel on a scheduled basis. Standardized laboratory checklists will be used during the inspections to document the inspections.

4.1 General Laboratory Inspection Plan

The General Laboratory Inspection Plan prescribes routine inspections of all laboratory facilities in accordance with the established schedules. The General Laboratory Inspection Plan will include: 1) a daily safety check conducted by EHS. The safety check is performed to verify the operational readiness of critical life safety support systems for the BSL-4, 2) a biannual comprehensive inspection and verification plan conducted by EHS and, 3) a biannual inspection plan conducted by the Core Supervisor.

4.1.1 Daily Safety Check

EHS conducts a daily safety check of systems critical to maintaining safe containment operations and life safety systems in BSL-4 laboratories (Appendix A)

4.1.2 Core Biannual Laboratory Inspection Plan

The NEIDL's BSL-4 program is organized into Cores, each being headed by a Core Director and with a Core Supervisor. Each Core has a defined research focus and function that includes the use of specialized equipment and procedures. The biannual laboratory inspection by each Core is customized and focuses on their facility and processes to ensure that each Core operate a safe laboratory facility environment. The Core Director is responsible for reviewing the findings of the inspections and work with EHS to conduct immediate remedial actions necessary to correct the findings. EHS will verify the compliance with this requirement during their routine inspections.

4.1.3 EHS Biannual Comprehensive Laboratory Inspection Plan

Twice per year, representatives EHS and Quality Personnel will conduct a comprehensive laboratory inspection to ensure that the BSL-4 environment is safe and in compliance with applicable laws, guidelines, and University procedures (Appendix B). As part of these inspections, EHS will inspect and evaluate BSL-4 CDC Select Agent and Toxins inventories under this plan to ensure the safety and security of these agents. The inspection is based on the CDC/USDA *Inspection Checklist for BSL-4 Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; BMBL 5th Edition).*

As a general rule EHS staff will:

- Become familiar with all permits (e.g., biological, radiation) issued to the PI as well as the requirements and limitations of each permit, including the most current transmittals to and from the PI.
- Become aware of the objectives and procedures of the PI's research encompassed by the Radiological Use Authorization (RUA), Biological Use Authorization (BUA), etc., and the associated health and safety issues.
- Review previous audit reports, and note deficiencies found, the lab's response to the audit report, and the measures implemented to correct the deficiency.
- Assemble the appropriate CLAS forms and materials. Carry a sufficient supply of appropriate posting (e.g., hazard signs), forms (e.g., protocol modification forms), and warning labels to be able to rectify deficiencies while in the laboratory.
- Schedule opening and exit interviews for the audit with the PI or Core Supervisor, making certain that person will be present during the inspection.
- Perform the audit. Using the standard checklist, explain each item to the laboratory representative, or others from the laboratory.

Note: A successful inspection should include a good explanation of items checked, the reason, and requirements. This also could be documented as part of an ongoing training program.

- Complete ALL necessary forms needed to fix potential problems identified while with the laboratory representative.
- If deficiencies are identified, provide clear and concise instructions to assist the laboratory in minimizing the hazard and achieving compliance, and note the deficiencies (and real-time resolutions) in the inspection report.
- Pay close attention to repeat or uncorrected previous violations. When necessary, follow up to ensure that matters to be corrected are referred to the PI.
- At the conclusion of the audit, review the results with the PI or Laboratory Safety Representative and discuss a means of compliance and a closure date for any open deficiencies.

4.2 Facility Operations Inspection Plan

In conjunction with the laboratory safety inspection conducted by EHS and authorized individuals, BSL-4 laboratory operations are safeguarded by equipment and system inspections conducted by Facilities Management & Planning. Facilities staffs perform daily checks of critical systems that consist of a walk-down checklist and recording information about some equipment (i.e. breathing air compressors) for trending purposes. Periodic checks of laboratory are inspections performed by in-house and contracted personnel on regular schedules. In-house, the inspections include laboratory walkthroughs to identify wear and tear within the BSL-4 and addresses, at a minimum, the utilities, coatings, and the secondary barrier. Necessary repairs are performed during live laboratory operations or when the suite is shutdown during annual recertification. Control center technicians monitor the status of all mechanical, electrical, and plumbing support systems (i.e., HVAC, waste treatment). Any alarms or notifications are relayed to NEIDL Facilities staff under the direction of the Director, NEIDL Facilities. An appropriate course of action ranges from further observation to immediate closure of an affected laboratory zone. In the case of the latter, critical information and operational procedures will be immediately relayed to laboratory personnel through visual strobes, television monitors, or other means.

All inspection and maintenance data are evaluated at least annually as part of the recertification process see Section 4 - BSL-4 Laboratory Commissioning.

5.0 INSPECTION PROGRAM FOR THE BSL-4 LABORATORY ENVIRONMENT

The BSL-4 Laboratory Inspection Program is a body of plans and procedures to ensure the safety of personnel working at the NEIDL by assessing hazards and compliance, and monitoring system integrity. For each inspection plan (described in section 4 of this document), designated inspectors will visit all

areas assigned and will communicate all findings and recommendations verbally during an inspection to the responsible operational personnel. Following an inspection, written reports will be sent to the PI and Core Director. Findings that are related to the Core facility, equipment and processes will be addressed by the Core Director. Those findings that are project specific and procedures performed by the PI will be addressed by the PI. The Core Director, PI and EHS will ensure that findings within the Core are communicated to ensure that they are addressed in a timely manner. As necessary, copies of the reports will be forwarded to the Director, NEIDL Facilities, and the NEIDL Associate Directors, and/or the respective Dean, as appropriate. A report includes a summary of findings and recommended actions. The PI is required to respond to the findings in writing, describing corrective actions taken to remedy any deficiencies identified as well as a plan to prevent their recurrence.

5.1 Life Safety Systems

Surveillance cameras can be used to monitor the BSL-4 laboratories at all times. Laboratory personnel are trained on life safety and security processes and on proper entry to the secured areas that they are authorized to access and work in. Laboratory personnel, together with EHS, help monitor the safety and security of the laboratories through inspections and reviews and ensuring that personnel consistently follow procedures.

There are two aspects of the laboratory environment being monitored. The first consists of the inanimate physical components that make up the BSL-4 domain. The second consists of the laboratory activities that take place within that domain. Inanimate physical components warranting inspection or monitoring for safety purpose include primary barriers and secondary barriers. Laboratory activities warranting monitoring include standard operating procedures carried out by BSL-4 authorized individuals.

5.1.1 Protective Breathing Air Suits

The Personal Protective Equipment required for BSL-4 activities includes positive pressure suits, which are fed with air through breathing air compressors and include a High Efficiency Particulate Air (HEPA) filtration system. All authorized personnel entering BSL-4 laboratories will be required to inspect the integrity of their suits before entering biocontainment. Training for suit inspection and maintenance will be an integral part of BSL-4 training and required for BSL-4 access.

5.1.2 Breathing Air System

Triplex electrical driven compressors serve as the primary source of breathing air, with a high-pressure reserve system supplying 20,000 CF of breathing air as backup in the event of a failure of the primary and reserve supplies. The system is monitored in real time for available pressure (capacity) and alarmed to the BSL-4 laboratories' Critical Alarm. Recurring testing of this system is included in the inspections conducted as part of the Facilities Operations Inspection Plan. Breathing air quality is continuously monitored by

BAS and samples are taken (from both the primary and backup breathing air systems) for analysis annually.

5.2 Primary Containment Barriers

Primary containment barriers represent the innermost confines within which Select Agents and Toxins are handled. These confines include Biological Safety Cabinets and isolators.

5.2.1 Class II Biological Safety Cabinets

Class II Biological Safety Cabinets (BSCs) are used to prevent the researcher and the surrounding environment from being exposed to potentially dangerous or infectious biological material. There are three types of Class II BSCs in use:

1. Class II type A2 (BSL-4 labs)
2. Class II type A1 (ABSL-4 cage-changing BSCs in animal housing rooms)
3. Class II type B1 (ducted BSCs in necropsy suites)

The PI is responsible for maintaining the operational integrity of the BSC and for ensuring that a pre-use inspection is completed. EHS is responsible for ensuring that all BSCs are tested and certified on an annual basis and for maintaining certification records.

5.2.2 Class III Biological Safety Cabinet

Class III Biological Safety Cabinets are used to work with microbiological agents in the BSL-4 cabinet laboratories and provide maximum protection to the researcher and environment. Workers are able to manipulate the infectious agents that are isolated in a Class III BSC using arm-length, heavy-duty hypalon gloves that are attached in a gas-tight manner to ports in the Class III BSC. The Class III BSC is visually inspected before each start of use, including the gloves used for manipulation and the internal pressure displayed on gauges on the outside of the Class III BSC. The inspection is recorded on a logbook. The gloves are replaced at least twice a year and pressure decay test is performed at each glove replacement. The unit is equipped with gauges and alarms to notify the user of a malfunction that must be monitored and to ensure operations within the established parameters. After the completion of the research study and before the start of a new study, the BSC is decontaminated with VHP and the decontamination is validated with biological indicators (BI). The Class III BSC will be inspected by EHS biannually, during the mandatory glove change and recertified at least once a year. Each study performed in the Class III BSC is carefully reviewed by EHS with the scientific users as part of the risk assessment procedure. Recertification of the Class III BSC may be performed on a more frequent basis (i.e. two times per year) based on the risk assessment analysis of the studies.

5.2.3 HEPA Filtered Transport Isolators

HEPA-filtered, battery-powered transport isolators provide maximum protection to personnel and the environment as infected animals are transported from the Class III BSC to the ABSL-4 animal facility. Workers are able to handle animals inside the isolator using arm-length, heavy-duty hypalon gloves that are attached in a gas-tight manner to ports in the isolator. The animal workers and research personnel are responsible for cleanliness and upkeep of the isolator. The isolator equipment, gloves, pressure gauge, and docking are inspected prior to each use. The inspection will is recorded on a logbook. The gloves are replaced at least biannually. The equipment is equipped with an alarm and is monitored in the event of a malfunction during use. The isolator will be routinely tested and maintained, including integrity testing of the HEPA filters. The isolator is surface decontaminated with disinfectant at the end of each use, and is gas/vapor decontaminated at the end of each study.

5.3 Secondary Barriers

The boundary of the BSL-4 laboratory is defined by several barriers referred to as the secondary barrier that includes the concrete structure, windows, doors, and inward directional airflow/pressure differentials created by the HVAC system. Disruptions in the secondary barrier for entry/exit, waste management, and utilities are important features of the barrier that also require monitoring, routine inspection and maintenance.

5.3.1 Pressure Differentials and Directional Airflow

The BSL-4 environment operates on an active pressure control system. Each of the isolatable BSL-4 zones operates independently of the zones around it to maintain a negative pressure set point. Each zone is monitored and alarmed separately. If a zone fluctuates above or below the set point by a predetermined value, the individual zone will go into shutdown mode and close the bio-seal dampers, which seal the zone. Continuous monitoring of this system is a function of the Building Automation System (BAS) and the control center technicians. The system is also inspected and maintained at least annually.

5.3.2 Supply, Exhaust, and Filtration Systems

The HVAC system serving the BSL-4 laboratories consists of air handling units and exhaust fans operating with a system configuration of an N+1 redundancy. The systems are under active control and monitoring, maintaining required air flow for the laboratory. Pressure drops across these filters are actively monitored by the building automation system and will alert the operators if they exceed a specified set point. Each filter is also equipped with visual gauges allowing visual inspection. The recurring visual inspection of this equipment is part of the Facility Operations Inspection Plan (refer to section 4.2 above).

5.3.3 Seals, and Gaskets

The BSL-4 laboratory perimeter is defined by the secondary barriers. The secondary barrier, with respect to the laboratory proper, is the envelope created by the integration of all the secondary barriers. Penetrations of the barrier (e.g., to allow electrical or plumbing utilities) are sealed (caulked) or gasketed. Similarly, containment devices must be sealed or gasketed. The seals are installed under a strict quality control program ensuring their applicability and proper installation. The materials installed have been selected for compatibility with the chemicals used in research and decontamination methods. Once installed, the barriers are visually inspected as part of the ongoing Laboratory Inspection Plan. The inspection process includes a review of barriers and fittings for physical damage and may employ visual aids such as smoke or soap to investigate possible leak points.

5.3.4 Coatings

Although not a secondary barrier itself, the epoxy coatings on the floors, walls, and ceilings form a liquid repellent, easily cleanable, continuous shell on the concrete structure of the secondary barrier. This prevents liquids from being absorbed by the concrete that forms the barrier. The coatings are also visually inspected as part of the ongoing laboratory inspection plan.

5.3.5 Autoclaves

The BSL-4 facility is equipped with several pass-through autoclaves. Personnel who operate the autoclaves must be properly trained to operate them safely and conduct decontamination validations. Results of testing and monitoring must be kept and updated in a log for recordkeeping. EHS and the Quality Representative review the waste decontamination and autoclave maintenance records during inspection.

5.3.6 Liquid Effluent Decontamination System

Prior to its operation, the Effluent Decontamination Systems (EDS) were initially tested. Tank temperature mapping and process cycle validations using biological indicators were performed. Post initial validation tests, each treatment tank cycle are verified quarterly with biological indicators inserted into the wells. The verification records are kept in the log in the EDS control room and are reviewed by the QR. All liquid effluent from the BSL-4 laboratories are treated with chemical disinfectant (e.g., 5% Microchem Plus) prior to final disposal into the EDS. Once the EDS tank is full, the liquid waste is heated and maintained at 121°C for one hour. Following system confirmation of successful sterilization at the end of each run, the effluent is cooled and discharged into the pH neutralization system. The entire EDS batch system is automated and will not permit any discharge to the pH neutralization system if all of the programmed parameters of time,

temperature, and pressure are not achieved. Thus, the treatment cycle is monitored at each run, and both printed records and electronic records are generated. All batch records for the physical parameters of each run are inspected and signed by EHS.

5.4 Records Management

All records of maintenance, repairs, testing, and validations must be maintained and updated in accordance with the program requirements. Select Agents, chemicals, and controlled substances must be properly inventoried. Inventories must be maintained and kept up-to-date. Select Agents and Toxins inventory records must be secured and will be reviewed routinely by the RO. EHS and the Quality Representative will review inventory records during inspections. Access control records for the BSL-4 facility will be maintained and kept up-to-date. Public Safety will control access based on approved access permissions. EHS and the Quality Representative will review access records during inspections.

6.0 EMERGENCY RESPONSE PREPAREDNESS

Emergency Response Planning (ERP) will ensure a prompt emergency response to incidents within the NEIDL (specifics are described in the EHS Comprehensive Emergency Management Plan). ERP, working with the Director of Research Safety, the PI, and the Quality Representative, will participate in the Laboratory Inspection Program. The ERP inspection program will entail reviewing training records and laboratory inspection results. ERP will ensure that the members of the NEIDL Emergency Response Team (NEIDL ERT) are current in their training requirements.

7.0 TRAINING RECORDS

The training requirements for BSL-4 activities are described elsewhere (see Section 15: BSL-4 Training Plan of the BPHC Biological Laboratory Safety Permit Application). EHS and the Quality Representative will inspect personnel training records to ensure that all staff are current with their required training and retraining requirements.

8.0 INSPECTION REPORT AND FOLLOW-UP

Following inspection, a written and electronic inspection report will be provided to laboratory contacts, outlining the results of the inspection and any recommended corrective actions. The inspector will require that work cease immediately when findings involve critical life safety systems and laboratory containment barriers. Such issues will be corrected immediately, and reviewed and verified by EHS prior to any resumption of work. Inspectors will also verbally communicate findings that are deemed as non-critical and needing improvement followed up with a written report. The PI (or Core Director) is required to respond to EHS and indicate the corrective action plan. EHS will follow up and verify that all corrective actions were completed.

8.1 Corrective Actions

Items that are found deficient during laboratory inspections will be documented in the inspection report. This report will include an explanation of the findings, that corrective actions are needed, who the responsible party is, and the target date for correction. When an item is corrected, the responsible party enters the date, name, and any comments into the report. Items found deficient concerning other departments (i.e., FMP, EHS) will be addressed by the appropriate representatives. All issues involving critical life safety and laboratory containment will be immediately corrected prior to any resumption of use or work.

8.2 Follow-Up Procedure

It will be the responsibility of the laboratory, FMP, EHS, etc., to ensure that all deficiencies are corrected as soon as possible. A corrective action plan will be agreed upon and include a time line for remediation. Deficiencies that are critical to biocontainment and safety will be corrected immediately. Follow-up inspection will be conducted based on the corrective action plan to ensure that the required actions have been completed. EHS staff will assist laboratory personnel in correcting deficiencies that need to be addressed. In the event that a laboratory is non-responsive to correcting deficiencies in the lab, the matter will be referred to the IBC for review and potential additional citations, suspension, or revocation of approval. Depending on the nature of the uncorrected deficiencies, a laboratory may be suspended from further research activities until the matter is resolved.

Note: Certain operational health and safety or critical equipment deficiencies will require shorter corrective action time lines and may result in suspension of the operations until the deficiencies have been corrected.

9.0 DEFINITIONS

Authorized Individual: A person who is approved by the Department of Health and Human Services (DHHS) Secretary or USDA APHIS Administrator and the BU Responsible Official to have access to the possession and use of Select Agents and Toxins at the NEIDL, based on a Security Risk Assessment by the U.S. Attorney General.

Principal Investigator (PI): An authorized individual approved by the Responsible Official (RO) to direct a Select Agents and Toxins project or program and who is responsible for the scientific and technical direction of that project or program

Risk Assessment: A process using qualitative and quantitative techniques to assess: 1) the potential for loss, theft, or release of a Select or non-Select Agent or Toxin from a containment laboratory, and 2) the risk to the public health from such loss, theft, or release. The risk assessment provides the basis for selecting security control measures to safeguard the public health.

Responsible Officer (RO): An authorized individual with responsibility, authority, and control to ensure compliance with the DHHS and USDA Rules and Regulations pertaining to the possession, use, and transfer of Select Agents and Toxins.

Select Agents and Toxins: Biological agents or toxic materials that have the potential to pose a severe threat to public health and safety. The DHHS Secretary and the USDA APHIS Administrator have responsibility for determining Select Agents and Toxins, which are listed in Title 42 CFR Part 73.3 and in Title 9 CFR Part 121.3.

10.0 KEY REFERENCES AND RESOURCES

Boston University. *Institutional Biosafety Manual*. Revised November 2013. Office of Research Compliance.

Biosafety. in Microbiological and Biomedical Laboratories, 5th ed, Wilson, D. E, and L. C. Chosewood, eds., 2009, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health. Washington, D.C.: U.S. Government Printing Office. See especially Appendix A - Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, p. 290–325.

Appendix A

BSL-4 Daily Safety Checklist

XX Floor

Building Automation System, Effluent Decontamination System and Tissue Digester

Containment Status *(Building Automation System, BAS)* **Check Control Center printout of BAS alarms &/or EHS display**	**Alarm Status** ☐ *Clear* ☐ *Alarm(s)*
Indicate Alarms (and Issues Affecting Operational Status):	
Liquid Decontamination System *(Computer in control room)*	**Alarm Status** ☐ *Clear* ☐ *Warning (Yellow)* ☐ *Alarm (Red)*
Liquid Decontamination System Room Visual Inspection *(Indicate Conditions and Comments)*	
Tissue Digester	**Alarm Status** ☐ *Clear* ☐ *Alarm* **Alarm Type:**
Tissue Digester Room Visual Inspection *(Indicate Conditions and Comments)*	

XX Floor (Buffer Corridor)

Autoclaves and Dunk Tanks

Lab Autoclave SV-120 *(Room XXXX)*	**Alarm Status**	☐ *Clear* ☐ *Alarm*	**Control Power Status**	☐ *On* ☐ *Off*
Lab Autoclave SV-120 *(Room XXXX)*	**Alarm Status**	☐ *Clear* ☐ *Alarm*	**Control Power Status**	☐ *On* ☐ *Off*
Lab Autoclave SV-120 *(Room XXXX)*	**Alarm Status**	☐ *Clear* ☐ *Alarm*	**Control Power Status**	☐ *On* ☐ *Off*
Lab Autoclave SV-120 *(Room XXXX)*	**Alarm Status**	☐ *Clear* ☐ *Alarm*	**Control Power Status**	☐ *On* ☐ *Off*
Dunk Tank A *(Room XXX)*	**Level Within Limits**	☐ *Yes* ☐ *No*	**Conductivity ≥3,500 µS**	☐ *Yes* ☐ *No*
Rack Autoclave *(Room XXXX)*	**Alarm Status**	☐ *Clear* ☐ *Alarm*	**Control Power Status**	☐ *On* ☐ *Off*
Rack Autoclave *(Room XXXX)*	**Alarm Status**	☐ *Clear* ☐ *Alarm*	**Control Power Status**	☐ *On* ☐ *Off*
Dunk Tank B *(Room XXX)*	**Level Within Limits**	☐ *Yes* ☐ *No*	**Conductivity ≥3,500 µS**	☐ *Yes* ☐ *No*

Laboratory Visual Inspection *(Indicate Conditions and Comments)*

XX Floor

Breathing Air System: Compressors, Storage Tanks, Backup Systems and Quality Control

1	**Chemical Shower Air Compressor Header Pressure**	**35-45 PSI**	☐ *Yes* ☐ *No*
2	**Backup Breathing Air, High Pressure (Storage tank pressure)**	**1,800 – 2,650 PSI**	☐ *Yes* ☐ *No*
3	**Breathing Air Header Pressure**	**95-125 PSI**	☐ *Yes* ☐ *No*
4	**Chemical Shower Air Compressor 1**	**Power Status**	☐ *On* ☐ *Off*
5	**Chemical Shower Air Compressor 2**	**Power Status**	☐ *On* ☐ *Off*
6	**Regulated Breathing Air Pressure (Gauges near tags: BA 374, BA 372)**	**25-35 PSI**	☐ *Yes* ☐ *No*
7	**Breathing Air Compressor (BAC-1)**	**Alarm Status**	☐ *Clear* ☐ *Alert* ☐ *Alarm*
8	**Breathing Air Compressor (BAC-2)**	**Alarm Status**	☐ *Clear* ☐ *Alert* ☐ *Alarm*
9	**Breathing Air Compressor (BAC-3)**	**Alarm Status**	☐ *Clear* ☐ *Alert* ☐ *Alarm*
10	**Breathing Air Quality Control Towers (BAC-1AQ1)**	**CO Alarm Status**	☐ *Clear* ☐ *Alarm*
11	**Breathing Air Quality Control Towers (BAC-2AQ2)**	**CO Alarm Status**	☐ *Clear* ☐ *Alarm*
12	**Breathing Air Quality Control Towers (BAC-3AQ3)**	**CO Alarm Status**	☐ *Clear* ☐ *Alarm*

XX Floor

Chemical Disinfectant Storage System

Stock Chemical Levels	**Barrel #1**	☐ ¼ ☐ ½ ☐ ¾ ☐ *Full*	**Barrel #2**	☐ ¼ ☐ ½ ☐ ¾ ☐ *Full*
Mixing Tanks	**Conductivity (≥3,500 µS)**	**Mixing Tank #1** ☐ *Yes* ☐ *No*	**Mixing Tank #2**	☐ *Yes* ☐ *No*
Chemical Storage Tank Levels	**Tank # 1**	☐ ¼ ☐ ½ ☐ ¾ ☐ *Full*	**Tank #2**	☐ ¼ ☐ ½ ☐ ¾ ☐ *Full*

Clear To Enter: ☐ **Yes** ☐ **No (Explain)**

**** Name & Signature:**	**Date:** ☐ Su ☐ Mo ☐ Tu ☐ W ☐ Th ☐ F ☐ Sa **Time:**

Appendix B

EHS Biannual Inspection Checklist

Semi-Annual BSL4 Safety Inspection Form (Suit labs)

Version 2.4 June, 2014

Date:_____

Room:_____

Inspector:_____

Items to be checked before entering:

	RECORDS/RECORD KEEPING				
	Items reviewed Before Going Into Containment				
Reference	**Critical Systems**	**Yes**	**No**	**N/A**	**Comments**
	Review daily checklists for the breathing air system (compressors, storage tanks, backup systems [air bottles] and quality control (dryer & CO alarm status). Are trends present that might indicate critical maintenance/repair is needed?	❑	❑	❑	
	Training *up-to-date: initial/annual refresher (or retraining), & when procedure/policies change				
	Science program staff is up to date* with all required BSL4 training: 1. BSL4 simulator training 2. Mentorship program completed successfully	❑ ❑	❑ ❑	❑ ❑	
	Science program staff is up to date* with SA training	❑	❑	❑	
	Science program staff is fully familiar with current policies, practices/procs & SOPs -	❑	❑	❑	

	interview				
	Review laboratory-specific training records (i.e., training in practices and procedures specific to the lab., including equipment operation e.g., laser safety training, radiation safety training, etc)	❑	❑	❑	
	Staff is up to date* on agent-specific training	❑	❑	❑	
	Staff is up to date* with AED and CPR training	❑	❑	❑	
	Staff is up to date* on other required trainings	❑	❑	❑	Expand – specifics?
	Biosafety Plan, Laboratory Manuals & Standard Operating Procedures				
CFR: Section 12(d) The plan must be reviewed annually and revised if necessary	Biosafety plan is current and up to date. Revise if necessary	❑	❑	❑	
CFR: Section 12(d) Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan	Review results of drills and exercises. Revise biosafety/biosecurity plans accordingly	❑	❑	❑	
CFR: Section 12(d) The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident	Subsequent to any incident, review adequacy of any revisions to the biosafety plan	❑	❑	❑	
	Laboratory-specific manual readily available in the lab (electronically)	❑	❑	❑	
	Laboratory SOPs reviewed and updated as required annually	❑	❑	❑	
	Attenuated Strain Verification				
	Verification records for all incoming	❑	❑	❑	

	shipments of attenuated strains are in order				
	Integrated Pest Management				
BMBL: A10 An effective integrated pest management program is required	Records indicate that all areas have been actively monitored for pests, and treated according to schedule. Inspect for evidence that the program is effective	❑	❑	❑	

	RECORDS/RECORD KEEPING			
	Items Reviewed Upon Entry Into Containment			
	Select Agent Inventory	**Yes**	**No**	**Comments**
	Inventory corresponds with records	❑	❑	
	All documentation for SA acquisitions, inter- and intra-facility transfer, destruction or loss is in order	❑	❑	

	PERSONAL PROTECTIVE EQUIPMENT & PRACTICES				
	Suit Lab	**Yes**	**No**	**N/A**	**Comments**
	Inspect BSL4 worker suit-check weekly log. Are all issues reported and resolved?	❑	❑	❑	
	Overall suit condition. Is it acceptable? (Recommend replacement if there is evidence of imminent failure)	❑	❑	❑	
	Suits stored appropriately	❑	❑	❑	
	Sufficient supplies available for suit maintenance	❑	❑	❑	
BMBL: C2 Protective laboratory clothing such as scrub suits must be worn by workers before entering the room used for donning positive pressure suits	Protective lab clothing (e.g., scrubs, socks, and necessary supplies e.g., tape, baby powder, blunt ended scissors) available and worn by workers entering suit room	❑	❑	❑	
BMBL: C3 Inner gloves must be worn to protect against break or tears in the outer suit gloves	Inner gloves available and worn (always) – Direct observation & interview of personnel	❑	❑	❑	
BMBL: C3 Alternatives to latex gloves should be available	Non-latex gloves available	❑	❑	❑	
BMBL: C2 All laboratory clothing must be removed in the dirty side change room before entering the personal shower	All protective clothing removed in the dirty side (inner change) room before entering the personal shower	❑	❑	❑	
BMBL: C3 Inner gloves must be removed & discarded in inner change room prior to personal shower	Inner gloves must be removed & discarded in inner change room prior to personal shower	❑	❑	❑	
BMBL: C3 Do not wash or reuse disposable gloves … Dispose of outer	No reuse of disposable gloves.	❑	❑	❑	
BMBL: C4 Dispose of used gloves with other contaminated waste	Gloves disposed of properly. Decontaminated with other contaminated laboratory waste (according to lab SOP)	❑	❑	❑	
BMBL: B1 Used laboratory clothing must not be removed from the inner change room through the personal shower. These items must be treated as contaminated materials and decontaminated	Decontamination of used protective lab clothing (scrubs), recorded (autoclave log)	❑	❑	❑	

before laundering					
BMBL: C4 Decontamination of outer suit gloves is performed during operations to remove gross contamination and further minimize contamination of the laboratory	Decontamination of outer suit gloves is performed during operations to remove gross contamination and further minimize contamination of the laboratory – *Direct observation & interview of personnel*	❑	❑	❑	
BMBL: B1 Entry into the facility must be by means of secure, locked doors	Test door access to locker rooms (dummy card)	❑	❑	❑	
BMBL: B1 A logbook, or other means of documenting the date and time of all persons entering and leaving the laboratory must be maintained	Audit entry/exit logs and reconcile: 1 exit for every entry	❑	❑	❑	
BMBL: B1 BMBL: C2 All persons leaving the laboratory must take a personal body shower. Used laboratory clothing must not be removed from the inner change room through the personal shower. These items must be treated as contaminated materials and decontaminated before laundering	Decontamination of used protective lab clothing (scrubs), recorded (autoclave log). No evidence of used scrubs beyond the personal shower.	❑	❑	❑	

	FACILITY CONDITION				
Reference	**Walls, Ceiling & Floors**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D3	All penetrations in the internal shell of the laboratory, (suit storage room) and the inner change room must be sealed	❑	❑	❑	

Items to be checked within containment

	PRIMARY & SECONDARY BARRIERS					
Reference	**Chemical Shower** Rooms:229, 227, 221, 219, 213, 211	**Yes**	**No**	**N/A**	**Comments**	**Date Resolved**
BMBL: D1 A chemical shower must be provided to decontaminate the surface of the positive pressure suit before the worker leaves the laboratory	Door gaskets not compromised and in acceptable condition	❑	❑	❑		
BMBL: D1	Shower runs for 7 mins (time the cycle)	❑	❑	❑		
BMBL: D1	Doors cannot be opened (except via emergency release) if cycle is not complete	❑	❑	❑		
BMBL: D1	Door interlocks are fully functional (two doors cannot be open at the same time)	❑	❑	❑		
BMBL: D1	Concentration of disinfectant is confirmed to be as intended (perform grab sample and measure conductance >3.5 mS/cm)	❑	❑	❑		
BMBL: D1	Spray heads not clogged or malfunctioning	❑	❑	❑		

BMBL: D1 In the event of emergency exit of failure of chemical shower system a method for decontaminating positive pressure suits, such as a gravity fed supply of chemical disinfectant, is needed	Emergency gravity feed (deluge) shower is fully functional	❑	❑	❑		
	Emergency door release is fully functional	❑	❑	❑		
	Biosafety Cabinets (Class II)					
BMBL: D10 HEPA filtered exhaust air from a class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified annually and operated according to manufacturer's recommendations. Biological safety cabinets can also be connected to the laboratory exhaust system by either a thimble (canopy) connection of a direct (hard) connection	All BSCs have been certified within the last year	❑	❑	❑	Expiration Date(s): _____ Expiration Date(s): _____ Expiration Date(s): _____ Expiration Date(s): _____	
BMBL: D10 Provisions to assure proper safety cabinet performance and air system operation must be verified	Front grill and exhaust filter of Class II BSC is unobstructed, and BSC alarms when sash is raised above height required for normal operation	❑	❑	❑		
BMBL: D7 Two inline filters must be placed near each use point. Filters must be installed to permit in place	Vacuum pump fitted with in-line (hydrophobic) filter and 2 HEPA filters to filter any air drawn from BSC (check date on filters = <1yr?)	❑	❑	❑		

decontamination and replacement						
	Any vacuum lines used in BSC have in-line (hydrophobic) filters and disinfectant traps	❑	❑	❑		
	Vacuum traps on floor have secondary containment	❑	❑	❑		
	Correct sash height is indicated and used while working in a Class II BSC	❑	❑	❑		
	No open flames used inside cabinet	❑	❑	❑		
	Downdraft Table (Necropsy)					
	Drain is free running. No evidence of clogging with clotted blood, tissue or hair/fur	❑	❑	❑		
	The surface and internal trough of the table is clean (evidence that these are thoroughly cleaned and decontaminated after every use)	❑	❑	❑		
	Evidence that air is being drawn down into the table (smoke test)	❑	❑	❑		
	Autoclave	**Yes**	**No**	**N/A**	**Comments**	
	Autoclave log is complete, up-to-date and includes verification (per lab SOP)	❑	❑	❑		
	Integrity of bioseal not compromised & is in good condition	❑	❑	❑		
	Autoclave door gaskets in good	❑	❑	❑		

	order					
	Safety interlocks functioning and in good order	❑	❑	❑		
	Autoclave drain clean and free flowing	❑	❑	❑		
	Secondary container is approved for autoclave use (e.g., stainless steel)	❑	❑	❑		
	Protective gloves available (for handling hot items)	❑	❑	❑		
	Emergency Equipment & Supplies					
BMBL: D8 An eyewash station must be readily available in the laboratory	Eyewash available	❑	❑	❑		
	Emergency sled available for extraction of non-ambulatory personnel	❑	❑	❑		
	Spill kit available, fully stocked and contents within date	❑	❑	❑		
	Container of disinfectant available (and within date) for the emergency treatment of needlestick, or other sharps, injury	❑	❑	❑		
	HEPA filtered equipment					
BMBL: C1 Equipment that may produce aerosols must be contained in primary barrier devices that exhaust through HEPA filtration	All aerosol producing laboratory equipment fitted with HEPA filtration (or enclosed in a HEPA filtered containment device -	❑	❑	❑		

before being discharged into the laboratory…	*itemize in Lab equipment below*)					
BMBL: C1 … these HEPA filters should be tested annually and replaced as needed	Equipment (or containment devices) fitted with a HEPA filter - the filter has been tested or replaced within the past 12 months	❑	❑	❑	Equipment/ Filter Expiration Date(s): _____ Equipment/ Filter Expiration Date(s): _____ Equipment/ Filter Expiration Date(s): _____ Equipment/ Filter Expiration Date(s): _____ Equipment/ Filter Expiration Date(s): _____ Equipment/ Filter Expiration Date(s): _____	

	LABORATORY EQUIPMENT				
	Cell Sorter	**Yes**	**No**	**N/A**	**Comments**
	Used in a primary containment device	❑	❑	❑	
	Flow cytometer	**Yes**	**No**	**N/A**	**Comments**
	Decontamination log up to date (record of room decontaminations following completion of studies)	❑	❑	❑	
	Sonicator	**Yes**	**No**	**N/A**	**Comments**
	Used in a primary containment device	❑	❑	❑	
	Vortex	**Yes**	**No**	**N/A**	**Comments**
	Used in a primary containment device	❑	❑	❑	.
	Centrifuge	**Yes**	**No**	**N/A**	**Comments**
	Sealed rotor or centrifuge safety cups used	❑	❑	❑	
	Rotors, centrifuge safety cups and sample tubes opened only in BSC	❑	❑	❑	
	Shaker/Incubator	**Yes**	**No**	**N/A**	**Comments**
	Used in a primary containment device	❑	❑	❑	
	Homogenizer	**Yes**	**No**	**N/A**	**Comments**
	Used in a primary containment device	❑	❑	❑	
	Other – Specify: _____	**Yes**	**No**	**N/A**	**Comments**
	Used in a primary containment device	❑	❑	❑	
	Other – Specify: _____	**Yes**	**No**	**N/A**	**Comments**
	Used in a primary containment device	❑	❑	❑	

	FACILITY CONDITION				
Reference	**Walls, Ceiling & Floors**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D3	Walls, floors, and ceilings of the laboratory are sealed (no cracks or breaks in coatings)	❑	❑	❑	
BMBL: D3	All penetrations in the internal shell of the laboratory, (suit storage room) and the inner change room must be sealed	❑	❑	❑	

	CHEMICAL DISINFECTION				
	Decontamination and Spill Procedures	**Yes**	**No**	**N/A**	**Comments**
	Cleaning and sanitization schedule being followed - *check log*	❑	❑	❑	
BMBL:B7-a A spill procedure must be developed and posted within the laboratory	Spill procedure developed and posted in the laboratory	❑	❑	❑	
BMBL:B7-b Equipment must be decontaminated using an effective and validated method before repair, maintenance or removal from the laboratory	Equipment removal logs show compliance with decontamination requirements	❑	❑	❑	
BMBL:B7-c Equipment or material that might be damaged by high temperatures or steam must be decontaminated using a gaseous or vapor method in an airlock or chamber designed for this purpose	Review airlock and equipment decontamination logs	❑	❑	❑	
BMBL D12 Decontamination of all liquid wastes must be documented	Chemical decontamination of liquid wastes recorded (and logged) prior to sink disposal - *review records & conduct direct observation*	❑	❑	❑	

	STORAGE				
	Specimen Freezers* *For select agent inventory, see "Records". For select agent security, see "Biosecurity"	**Yes**	**No**	**N/A**	**Comments**
	Appropriate hazard labels applied (biohazard, toxic etc)	❑	❑	❑	
	Explosion safe units to be used If flammables are to be placed into the freezer	❑	❑	❑	
	If the freezer is an -80 degree unit or liquid nitrogen, protective insulated gloves must be available to handle contents	❑	❑	❑	
	Specimen Refrigerators* *For select agent inventory, see "Records". For select agent security, see "Biosecurity"	**Yes**	**No**	**N/A**	**Comments**
	Appropriate hazard labels applied (biohazard, toxic etc)	❑	❑	❑	
	Explosion safe units to be used If flammables are to be placed into the freezer	❑	❑	❑	
	Supplies	**Yes**	**No**	**N/A**	**Comments**
	Sufficient reserve supplies of required PPE are readily available	❑	❑	❑	
	Sufficient supplies of appropriate disinfectants are available	❑	❑	❑	
	Sufficient reserve supplies of autoclave, biowaste bags, sharps containers, and MPW boxes are available	❑	❑	❑	
	Lab supplies are not excessive and are properly stored	❑	❑	❑	

	WASTE MANAGEMENT				
	Biohazardous waste	**Yes**	**No**	**N/A**	**Comments**
	Floor bins not greater than 50% full	❑	❑	❑	
	Biohazardous waste is double-bagged (using biohazard waste bags) within a biohazard waste container	❑	❑	❑	
	Items that have been in direct contact with pathogen are autoclaved at end of the day irrespective of whether the container is less than 50% full	❑	❑	❑	
	Biohazardous waste containers remain closed or covered except when introducing waste items, and bear biohazard labels (prior to autoclaving)	❑	❑	❑	
	No excess accumulation of autoclaved waste in clean side of autoclave	❑	❑	❑	
	No excess accumulation of autoclaved waste in the "autoclaved biowaste storage area"	❑	❑	❑	
	No excess accumulation of autoclaved animal carcasses. Carcasses promptly removed to storage in the tissue digester anteroom for disposal (*check logs*)	❑	❑	❑	
	Chemical waste	**Yes**	**No**	**N/A**	**Comments**
	Chemical wastes tagged, labeled with accumulation start date, full chemical names, amount disposed of, dated (< 60 days from start date) and kept closed	❑	❑	❑	
	Chemical waste containers in secondary containment	❑	❑	❑	
	Incompatible waste streams segregated (e.g., sodium hydroxide, hydrochloric acid)	❑	❑	❑	
	Mixed waste (biohazardous/chemical waste) biologically decontaminated before disposal as hazardous chemical waste	❑	❑	❑	
	Radioactive waste	**Yes**	**No**	**N/A**	**Comments**
	Radioactive waste disposal log for each isotope used	❑	❑	❑	

	Radioactive wastes cannot be held in the laboratory for more than 6 months. Check dates on any radioactive waste containers	❑	❑	❑	
	Mixed waste (biohazardous/radioactive waste) biologically decontaminated before disposal as radioactive waste	❑	❑	❑	
	Biosafety Cabinet Practices & Procedures	**Yes**	**No**	**N/A**	**Comments**
BMBL: C1	In a BSL4 suit lab all manipulations of infectious agents must be performed within a BSC or other primary barrier system (*direct observation*).	❑	❑	❑	
BMBL: C1	In a cabinet lab all manipulations of infectious agents must be performed in a Class III BSC (*direct observation*).	❑	❑	❑	
	Procedures used in the BSC are consistent with appropriate BSC use SOP (*direct observation*).	❑	❑	❑	
BMBL: C1	Manipulation of high concentrations or large volumes of infectious agents within a Class III BSC cabinet should be performed using physical containment devices within the cabinet.	❑	❑	❑	
BMBL: C1	Infectious agents in high concentrations or large volumes should be centrifuged in the cabinet (Class III) using sealed rotor heads or centrifuge safety cups	❑	❑	❑	
	All aerosol producing equipment are used in a BSC or other suitable containment device (unless otherwise approved)	❑	❑	❑	
	Biosecurity	**Yes**	**No**	**N/A**	**Comments**
	All aspects of physical security are functional and effective (e.g., SA level: locked freezers, refrigerators, incubators, lock-boxes; Lab level: card readers, biometric readers, video surveillance)	❑	❑	❑	

	GENERAL LABORATORY PRACTICES & PROCEDURES				
	Signage				
BMBL: A9	A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present	❑	❑	❑	
BMBL: A9	Posted information is current and includes the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entry/exit	❑	❑	❑	
BMBL: A9	Agent-specific information is posted in accordance with BU policy	❑	❑	❑	
	Proper additional signage is present on door (e.g. NFPA diamond, laser, strong magnetic field, etc)	❑	❑	❑	
	Lab equipment properly labeled for hazard (biohazard, radioactive, toxic etc.)	❑	❑	❑	
BPHC requirement	Boston Public Health Commission permit valid and posted	❑	❑	❑	
BMBL: B7-a A spill procedure must be developed and posted within the laboratory	Spill procedure is posted within the laboratory	❑	❑	❑	
	General Laboratory Housekeeping				
	Lab cleaning and sanitization schedule is being followed (no missing entries to log)	❑	❑	❑	
	Lab appears clean and uncluttered. No excess equipment/supplies in BSL4 labs	❑	❑	❑	
	In the absence of any alternative to glass, any glass containers brought into containment should not be on floor and should be coated so as to contain glass shards should it break	❑	❑	❑	
	No slip, trip or fall hazards present	❑	❑	❑	
	Sharps Management				
BMBL: A5-c	Used needles must not be bent, sheared, broken, recapped, removed from disposable	❑	❑	❑	

	syringes, or otherwise manipulated by hand before disposal or decontamination				
BMBL: A5-c	Used disposable needles must be carefully placed in puncture –resistant containers used for sharps disposal, located as close to the point of use as possible	❑	❑	❑	
BMBL: A5-a Broken glass ware must not be handled directly. Instead, it must be removed using brush and dustpan, tongs or forceps	Dustpan, tongs and forceps are readily available in the spill kit (for cleanup of sharps).	❑	❑	❑	
	Sharps containers not overfilled.	❑	❑	❑	
	Sharps stored appropriately. (*Reusable sharps e.g., necropsy tools decontaminated and stored in puncture resistant container*)	❑	❑	❑	
	Chemicals				
	Chemical inventory is up-to-date	❑	❑	❑	
	Chemical containers decontaminated before removal from BSL4 lab	❑	❑	❑	
	Flammables in flammable storage cabinet	❑	❑	❑	
	Corrosives stored in corrosives storage cabinet or in secondary container (if no corrosives cabinet available)	❑	❑	❑	
	Peroxide formers double dated (receipt/opened). Tested trimonthly. Peroxide formers held only for 1 year.	❑	❑	❑	
	Chemicals segregated properly	❑	❑	❑	
	No chemicals stored on the floor	❑	❑	❑	
	Chemical containers not left open	❑	❑	❑	
	All solutions properly labeled	❑	❑	❑	

	Electrical				
	No frayed or damaged wiring on equipment	❑	❑	❑	
	No overloaded outlets	❑	❑	❑	
	No electrical power connections close to floor (in case of lab flooding)	❑	❑	❑	
	Gas Cylinders				
	No gas cylinders introduced into BSL4 without approval	❑	❑	❑	
	All cylinders secure	❑	❑	❑	
	Caps on reserve cylinders	❑	❑	❑	
	Cylinders tagged “Full,” “Empty,”and “In-Use”	❑	❑	❑	
	No excess cylinders (full or empty)	❑	❑	❑	
	Fire Protection				
	Mist and regular fire suppressant systems checked and functioning within design limits	❑	❑	❑	
	Alarm system checked. All alarms (lights/sirens) and call outs operational	❑	❑	❑	
	Sprinkler heads free, unobstructed, 18” clearance below heads	❑	❑	❑	
	36” minimum passage widths in room. No equipment, supplies or caging obstructing passageways	❑	❑	❑	
	All lab doors kept closed (directional airflow, and fire protection ensured)	❑	❑	❑	
	No excess combustibles (cardboard, paper etc) present	❑	❑	❑	